K051921

JUL 27 2005

510(k) Premarket Notification Summary

Contact:	Noel Downey
Date:	April 1, 2005
Trade Name:	The Edge™ – Scanning Diode Detector
Common Name:	Scanning Diode Detector
Substantial Equivalence:	PTW Dosimetry Diode and the PTW Pinpoint Type Ionization Chamber

Description and Use:

The Edge™ detector is a radiation hardened silicon diode. The diode is encapsulated in a rectangular housing made of thin brass sheet. The active dimension of The Edge™ detector is 0.8 x 0.8 mm2. The diode die plane is parallel with the long axis of the detector housing with the center of the die marked by the cross on the top surface. The detector is mounted such that its top surface is parallel to the water surface and perpendicular to the incident radiation beam axis. The Edge™ detector is water-proof.

The Edge™ detector is designed to measure the radiation distribution in a water phantom. Because of its very small active dimension, The Edge™ detector can measure small field beam parameters, such as penumbra and flatness, more accurately than the conventional ionization chamber with larger active dimensions. Therefore, The Edge™ detector is especially useful for beam modeling in radiation therapy techniques involving small field sizes, such as IMRT (Intensity Modulation Radiation Therapy).

Similarities and differences between SNC The Edge™ Scanning Diode Detector and PTW Diode and PTW Chamber:

The Edge Detector, PTW Dosimetry Diode and PinPoint Ionization Chamber can be used to measure the radiation beam data in water phantoms for treatment planning in a radiation department. Their similarities are:

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Similarities with Marketed Devices:

1. Their intended use is essentially the same.
2. They all connect to electrometers with a water phantom system.
3. They are all Water-proof.
4. They all measure the same beam energies.

Differences with Marketed Devices

There are no fundamental differences among these detectors in terms of their overall functionality. Their design and operation are somewhat different:

1. The active dimension is 0.8 mm for the Edge detector, 1 mm for the Dosimetry Diode, and 2 mm for the PinPoint chamber.
2. With respect to the beam axis, the axis of the Edge detector and the PinPoint chamber is perpendicular, the axis of the Dosimetry Diode is parallel.
3. There is a high voltage (~ 300 V) required for the PinPoint ionization chamber, while there is a "zero" voltage (< 10 μV) required for the Edge detector and the Dosimetry Diode.
4. Dosimetry Diode uses p-type diode, while Edge detector uses a special radiation hardened n-type diode.
5. Dosimetry Diode and PinPoint chamber are in cylindrical shape, while Edge detector is rectangular.

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Safety and Effectiveness Summary for Edge detector

Edge detector is only used by the radiation therapy professionals, it is not used with the patient. The Edge detector is designed to be used with zero bias voltage when connecting to an electrometer, and thus should not generate electrical shock hazard to the operator.

Sun Nuclear has deemed the devices safe and effective for their intended uses as long as they are used in accordance with all of the accompanying labeling and instructions. When used properly, Edge detector can collect the useful dosimetry modeling data for radiation therapy treatment planning. Sun Nuclear believes that responsible design and quality assurance practices were followed during the development and manufacture of Edge detector (Model 1118000-0).

Safety features of Edge detector

Feature	Effect
1. No bias voltage applied	Eliminate electrical shock hazard and excessive leakage current
2. Low noise cable	Provide stable measurement and low leakage
3. Shielded housing	Provide stable measurement

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2005

Mr. Noel M. Downey
Project Manager
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940

Re: K051921
Trade/Device Name: The Edge™ Detector
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 14, 2005
Received: July 15, 2005

Dear Mr. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K051921

Device Name: The Edge™ Detector

Indications for Use:

The Edge™ Detector is a device that is designed for use as a radiation scanning detector in any water tank scanning system that is used to measure beam data in radiotherapy departments for dose modeling in the treatment planning computer.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use _____

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051921